# FREQUENTLY ASKED QUESTIONS

**QUESTION 1: Is the enhanced risk management program centralized or decentralized?**

ANSWER: In a sense it is both, as the overall goal of the program is to be comprehensive. The NIH Director and CFO are responsible every year for providing public assurances that all NIH programs are being managed effectively, efficiently, and prudently—in accordance with all applicable laws and regulations. However, the actual management of these programs takes place throughout the whole organization.

The new program plan makes it clear that managers and employees at all levels of the organization have a fundamental responsibility for risk management, and play critical roles in ensuring the integrity of NIH programs. Risk management measures have been, or should be, put in place in all NIH programs to help ensure high quality management and expected results all the way down to the individual transactions required to get the job done. The managers assigned to each program have leadership responsibility for seeing that these controls are put into place and using them as part of their normal duties so as to reduce risks of waste, fraud, and abuse, and to guard against other unwanted and illegal results of program deficiencies. Assessments will be undertaken by the Office of the Director or at the ICs to assure that these controls are working as intended. Everyone at NIH—from top to bottom—must work together to ensure that risk management is effective.

Standards of program integrity are, or should be, imbedded in the processes and procedures that guide each program. Some of these standards are government-wide. Others emanate from DHHS or NIH. Still others come from professional standards and accepted "best practices" in the program field itself. Each process or procedure should incorporate risk management to ensure that the applicable standards are being adhered to, or that departures from the standards will be reported and corrected. The idea is to catch departures from standards early, closest to the transaction level, and correct them before significant damage is done to the program or the agency.

**QUESTION 2: What is the relationship of the new enhanced program to the existing risk management program?**

ANSWER: The existing program provides the foundation of the enhanced program. Over the years, NIH has recognized the potential for risks in some 50 program areas. This list is not static, and the levels of risk are by no means equal from area to area. Thus, each area needs to be continually assessed and addressed in accordance with the level of risk it presents. However, the new program, while refining this list and assuring that it is comprehensive across the major functions of NIH, also integrates risk management into the NIH management and governance structure to assure the priority and accountability that is required to adhere to the intent of OMB Circular 123. In this regard:

- The program is linked directly to, and will be overseen by, the NIH Steering Committee (SC), working with the Management and Budget Working Group, and the other Work Groups as needed
- The assessment program is more comprehensive. This program recognizes that NIH risk areas cut across its administrative, intramural, and extramural programs as well as

IC-specific programs. The program is structured to assure that equal focus and priority is accorded to identifying and assessing risks in each of these areas.

- The assessment program is more rigorous. The SC will select those NIH-wide areas that are the highest priority for assessment on a yearly basis. The OMA will either conduct or oversee the conduct of the assessment of each of these areas and will report the findings and any need for follow-up action to the SC. At the same time, ICs will submit an assessment plan to OMA and conduct assessments for high priority risk areas that they have identified that are not scheduled for assessment by OMA.
- The program recognizes that risk management is every manager's responsibility and the role that should be played by automated systems. While previous risk management programs have often focused primarily on the assessment phase, the most important aspect of any such program is prevention—the integration of risk management into the normal day-to-day duties of every manager. In this regard, it is their responsibility to assure that automated systems incorporate risk management features and that reporting systems provide the information necessary for them to monitor the efficiency and effectiveness of their programs.
- This program places greater responsibility on the OD functional Deputy Directors, the CIO, and IC Directors. Each of these officials will be required to sign an assurance to the Director of NIH that a system of effective controls exists for their functions and programs.

**QUESTION 3: What incentives exist to encourage managers and employees to identify and assess risks, and to report violations of standards?**

ANSWER: The consensus of NIH officials consulted about enhancing the risk management program was that tying success with risk management to individual managers' performance plans, performance reviews, and performance pay would be the most practical means of providing incentives for good risk management performance. This approach relies on forming clear expectations about the controls to be applied, how they are to be tracked, and how corrective actions are to be initiated—at each level of responsibility. These controls are required by laws, increasingly strict standards, and better-publicized good practices.

Specialized software now coming on the market to help keep track of controls in each risk area may be helpful in comparing the current NIH control systems with best practices and encouraging improvements at NIH.

**QUESTION 4: What are some examples of controls that need to be improved? How would NIH go about making improvements?**

ANSWER: Significant effort has been undertaken, and must continue to be taken, to refine the list of NIH-wide high risk areas. One key step is the 2006 agency-wide risk assessment conducted by an outside consultant expert in bio-medical research issues. But this is an iterative process and the list must continue to be refined. The same is true for identifying IC-specific risk areas.

In identifying high risk areas, both for NIH-wide and IC-specific items, special attention might be given to areas that are now undergoing the most rapid and/or significant organizational or procedural changes. Change, itself, can raise the risk of activities, so those areas should be closely monitored as the changes occur—to make sure they are not going off the track.

Examples are the creation of new MEOs, reorganizing offices, moving large numbers of employees, and installing new information systems.

One way to begin examining the highest-risk areas would be to make sure that there are at least some quantitative measures for tracking the things that could go wrong in these areas, and a means of generating "red flag" reports to provide early warnings of when corrective actions may be needed to keep serious consequences from occurring. If there are no data available for this purpose now, surveys, quick evaluation studies, or special investigations could be used in the interim to make sure everything is OK while possibilities for establishing regular monitoring are explored.

The point is to try to make sure there are not some "surprises," waiting to be revealed without warning.

**QUESTION 5: The enhanced program sounds like a lot of new work—on top of everything else we are doing. How will we be able to fund it and do it?**

ANSWER: We are already funding and doing part of this work. The rest will need to be phased in as budgets permit. Some increased funding will be needed to meet increased requirements and expectations and to conduct the rigorous assessments that are planned, but we may also be able to find more efficient ways of monitoring controls as new automated systems come on-line. These systems are typically more efficient than ad hoc reviews.

Risk Management is not a new responsibility. Controls have been required for many years and a lot of work has been done on them. Much of that ongoing, already-funded work may be satisfactory now. Confirming that fact may be all that's required for some risk areas. Certainly, we should avoid fixing controls that are not broken.

At the same time, however, it should be acknowledged that much new work and some new funding may be needed in other areas—especially high-risk areas. Obviously, not all areas that need greater attention can be upgraded at once. A phased approach will be needed.

The enhanced risk management program endorsed by the SC provides for planning and funding a manageable program of enhancements each year, beginning with Fiscal Year 2006. The OD and IC business process "owners" having responsibilities in the high-risk areas chosen each year will be expected to assist in budgeting for and upgrading the risk management programs in those areas that affect them as they are scheduled. Over time, all the high-risk areas are expected to be upgraded in line with current best practices. Upgrades in other areas may also be desirable as time and resources permit.

As new IT systems are installed, special attention should be given by business owners to ensuring that they incorporate provisions for risk management, including appropriate data reporting, tracking, and red-flag early warning indicators.

**QUESTION 6: What is OMA's "independent assessment" role? Why is it needed? Is OMA qualified to make independent assessments of technical (medical science and clinical care) risk areas?**

ANSWER: OMA is NIH's designated evaluator of "management quality," much as the DHHS Inspector General holds that role for the department, and GAO for the whole government. Its

role will focus on management risks within the science programs, not the science itself. Other peer review mechanisms are available for assessing scientific issues. If scientific and management issues are inextricably intertwined, joint or parallel assessments may be required.

An independent assessment role is needed for two reasons. First, OMA is better placed to make broad, NIH-wide assessments than organizations with responsibilities for only portions of the risk area. Second, OMA is able to bring a degree of objectivity to the assessment role uncompromised by responsibilities for the particular programs being assessed.

OMA is qualified for this independent role by its long years of experience in making management assessments and benchmarking to find relevant best practices that could be utilized at NIH.

But, nevertheless, OMA's capacity will not be unlimited. It will focus largely on NIH-wide issues. The ICs will be expected to provide their own risk assessments and program evaluations to a significant extent.

**QUESTION 7: What help is available to us in performing the newly required risk management tasks?**

ANSWER: The risk management training on the OMA website, which already provided the basics, has been (is being?) expanded to cover more people, to cover more topics, and to target particular audiences—according to their particular roles in the risk management process. An analysis was performed to identify specific needs for these new offerings. And, best practices from other agencies and the private sector have been (are being?) incorporated.

In addition, OMA has developed (is developing?) a series of tools—check lists, forms, etc.—for use by those directly responsible for the formal risk management program, as well as for all employees as they carry out their daily activities.

NIH is also undertaking a general educational campaign to sensitize the whole NIH community to the benefits of sound risk management efforts that reduce the number and seriousness of things that go wrong at NIH. This effort is aimed at strengthening the NIH culture of quality management to bring expectations to a higher level. A community that actively supports risk management will, in itself, facilitate implementation of improved risk management efforts.

Links to the training and risk management tools are located on this web page.